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Exhibit 454

ORAL ARGUMENT NOT YET SCHEDULED
No. 15-1335

United States Court of Appeals for the District of Columbia Circuit

MASTERS PHARMACEUTICALS, INC.,
Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,
Respondent.

BRIEF FOR HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION AND NATIONAL ASSOCIATION OF CHAIN DRUG STORES AS *AMICI CURIAE* IN SUPPORT OF NEITHER PARTY

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to this Circuit's Rule 28(a)(1), *amici curiae* certify:

(A) *Parties and Amici.* Except for the following, all parties, intervenors, and amici appearing before the district court and in this court are listed in the Opening Brief of Petitioners: *Amici curiae* Healthcare Distribution Management Association and National Association of Chain Drug Stores.

(B) *Rulings Under Review.* References to the rulings at issue appear in the Opening Brief of Petitioners.

(C) *Related Cases.* *Amici curiae* are aware of no related cases pending in this Court or any other Court.

/s/ Gregory G. Garre
Gregory G. Garre

RULE 26.1 DISCLOSURE STATEMENT

Amicus curiae Healthcare Distribution Management Association is a not-for-profit trade association that represents the nation's primary, full-service healthcare distributors. *Amicus curie* National Association of Chain Drug Stores is a nonprofit trade association that represents chain community pharmacy companies, including traditional drug stores, supermarkets, and mass merchants with pharmacies.

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GLOSSARY

APA	Administrative Procedure Act, 5 U.S.C. § 551 *et seq*
CSA	Controlled Substances Act, 21 U.S.C. § 801 *et seq.*
DEA	Drug Enforcement Administration
HDMA	Healthcare Distribution Management Association
Final Order or Masters Final Order	*Masters Pharmaceuticals, Inc.; Decision and Order*, 80 Fed. Reg. 55,418 (Sept. 15, 2015)
Masters	Masters Pharmaceuticals, Inc.
MOA	Memorandum of Agreement
NACDS	National Association of Chain Drug Stores
Security Manual	Office of Diversion Control, U.S. Department of Justice, *Controlled Substances Security Manual*: *A Message from the Administrator*, http://www.deadiversion.usdoj.gov/pubs/manuals/sec/message.htm (last visited Mar. 29, 2016)
Southwood	*Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 Fed. Reg. 36,487 (July 3, 2007)

INTEREST OF *AMICI CURIAE*

Amicus curiae Healthcare Distribution Management Association (HDMA) is the national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors.[1] HDMA's members deliver lifesaving products and services, ensuring that 300 million United States consumers have continuous access to prescription drugs and other important products. HDMA's mission is to protect patient safety and access to medicines through the safe and efficient distribution of healthcare products and services. The actual decision to prescribe and dispense these drugs, however, is made by physicians and pharmacists, who use their medical training to assess individual patient needs. Distributors do not see patients, do not have access to individual patient data, and are not trained to make medical decisions about whether a drug should be prescribed or dispensed.

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[1] As required by Federal Rule of Appellate Procedure 29(c)(5), HDMA and National Association of Chain Drug Stores (NACDS) state that no party's counsel authored this brief in whole or in part, no party or party's counsel contributed money that was intended to fund preparing or submitting the brief, and no person other than HDMA, NACDS, their members, and their counsel contributed money that was intended to fund preparing or submitting this brief. Petitioner Masters Pharmaceuticals, Inc. (Masters) is not an HDMA member and has not otherwise contributed to HDMA for the preparation of this brief or any other purpose. Masters is an associate non-voting member of NACDS, but NACDS does not represent the interests of Masters and Masters has not contributed to the preparation of this brief.

HDMA has 34 distributor members. All of these distributors predominantly buy prescription drugs directly from manufacturers and predominantly distribute them directly to healthcare providers. Nearly all of them (and all that have an interest in this case) are also registered with the Drug Enforcement Administration (DEA) to distribute controlled substances that are contained in prescription drugs. These distributor members have a wide range of business models, including national and regional firms, and publicly traded and family-owned businesses. They include specialty distributors, firms that distribute "biologics" (such as vaccines) or oncology drugs that are often subject to special handling requirements, firms that service only physician offices, and firms that distribute only generic products. While HDMA members have a serious role and responsibilities in drug distribution, distributors do not prescribe or dispense these drugs to patients, and have no direct control over those who do.

Amicus curiae National Association of Chain Drug Stores (NACDS) is a 501(c)(6) nonprofit trade association. NACDS membership consists of chain community pharmacy companies, including traditional drug stores, supermarkets, and mass merchants with pharmacies—from regional chains with four pharmacies to national companies. NACDS members operate more than 40,000 pharmacies in the United States and employ 179,000 pharmacists. NACDS members fill more than 2.9 billion prescriptions annually and aid patients in taking their medicines

correctly and safely, while offering innovative services that improve patient health and healthcare affordability. As dispensers of controlled substances with a corresponding responsibility to guard against abuse and diversion, NACDS members are subject to significant DEA regulation. In connection with their commitment to patient care, NACDS members have zero tolerance for drug abuse and diversion and one hundred percent commitment to legitimate prescription drug access and patient care. The need to balance these two important priorities gives NACDS a significant interest in the important issues raised in this case.

The public health dangers associated with the diversion and abuse of controlled prescription drugs have been well-recognized by Congress, DEA, public health authorities, and others—including HDMA and NACDS and their members. HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society. HDMA and NACDS members, however, like all members of the regulated public, also have an interest in receiving notice of their obligations under federal law and, likewise, in the manner in which DEA promulgates, modifies, interprets, and applies its rules. Although HDMA and NACDS take no position on the proper resolution of this case or DEA's findings against Masters Pharmaceuticals, Inc. (Masters), they

submit this brief to address the broader concerns of prescription drug wholesale distributors and pharmacies that are raised by the issues presented in this case.

INTRODUCTION AND SUMMARY OF ARGUMENT

Administrative agencies are required to comply with the mandates of the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq*. Among other things, that means that an agency is bound by its own regulations. *Environmentel, LLC v. FCC*, 661 F.3d 80, 84-85 (D.C. Cir. 2011). That means that an agency cannot change its position without at least acknowledging and providing a reasoned explanation for the change. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). And that means that an agency cannot take a position that conflicts with its existing rules. *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015).

DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders). *See* 21 C.F.R. §§ 1301.71, 1301.74(b). But in certain recent pronouncements, including *Masters Pharmaceuticals, Inc.; Decision and Order*, 80 Fed. Reg. 55,418 (Sept. 15, 2015) (Final Order), DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders

before they are filled. Those added obligations would significantly expand the "report-only" duty of distributors under the longstanding regulatory scheme and impose impractical obligations on distributors, which occupy a fundamentally different position than the physicians who prescribe the drugs to patients or pharmacists who dispense drugs to fill those prescriptions.

Any attempt to impose such new obligations on distributors would have to be squared with settled administrative law principles. In particular, DEA could not change its position—and impose new obligations on distributors—without first acknowledging the change and providing a reasoned explanation for it. In addition, DEA could not adopt a position that is inconsistent with its own regulations without first engaging in notice and comment and amending its rules. Such notice and comment is not only required to avoid procedural and substantive invalidity, but it would enable DEA to consider the myriad healthcare and patient privacy-related issues raised by such a change in policy, as well as allow DEA to consider alternative, tailored anti-diversion solutions, after hearing from all interested parties, including the members of HDMA and NACDS.

ARGUMENT

I. AN AGENCY'S CHANGE IN POSITION IS INVALID IF THE AGENCY DOES NOT ACKNOWLEDGE THE CHANGE AND PROVIDE A REASONED EXPLANATION FOR IT

1. It is settled that an agency cannot change its position without at least acknowledging and explaining the change. As the Supreme Court has held, an agency must "display awareness that it *is* changing position" and "show that there are good reasons" for the change. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Huerta v. Ducote*, 792 F.3d 144, 153 (D.C. Cir. 2015) ("The Board's position will be deemed 'arbitrary and capricious if it departs from agency precedent without explanation.'" (citation omitted)); *Dillmon v. National Transp. Safety Bd.*, 588 F.3d 1085, 1089-90 (D.C. Cir. 2009) (The APA "requires the agency to acknowledge and provide an adequate explanation for its departure from established precedent."). Agency action that does not do so is "arbitrary and capricious." *Perez*, 135 S. Ct. at 1209.

2. The Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, allows the Attorney General to register entities to distribute controlled substances if, among other requirements, the distributor maintains "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1), (e)(1). DEA has promulgated regulations detailing the measures that distributors must take in order

to maintain effective controls. Specifically, "[i]n order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76." 21 C.F.R. § 1301.71(a). Those regulations, in turn, set out explicit requirements for maintaining *physical* security and also, most relevant here, require a registrant to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and then to report such suspicious orders to DEA. *Id.* § 1301.74(b).

At least until 2006, DEA consistently interpreted Section 1301.71 to require only that distributors *report* suspicious orders. For example, in 1991, DEA issued its Security Outline of the Controlled Substances Act for registrants, "outlin[ing] the steps needed to establish a competent security system which deters diversion and reduces accessibility for potential abusers." *See* Office of Diversion Control, U.S. Department of Justice, *Controlled Substances Security Manual: A Message from the Administrator*, http://www.deadiversion.usdoj.gov/pubs/manuals/sec/message.htm (last visited Mar. 29, 2016) (*Security Manual*). The *Security Manual* explains in detail the various "steps needed to establish a competent security system which deters diversion," *id.*, but does not include any obligation on the part of distributors to investigate and take action to halt suspicious shipments. Instead, the *Security Manual* states only that a registrant "must design and operate

a system to *disclose* suspicious orders of controlled substances" and "must *inform* the appropriate DEA Field Office of suspicious orders immediately upon *discovery*." *Id., Other Security Controls*, http://www.deadiversion.usdoj.gov/pubs/manuals/sec/other_sec.htm#sus_orders (emphasis added).

As the Final Order in this case underscores, however, DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. 80 Fed. Reg. at 55,421, 55,475-77, 55,479. Such a change in agency position must be accompanied by an acknowledgement of the change and a reasoned explanation for it. In other words, an agency must "display awareness that it *is* changing position" and "show that that there are good reasons for the new policy." *Fox Television Stations, Inc.*, 556 U.S. at 515. This is especially important here, because imposing intrusive obligations on distributors threatens to disrupt patient access to needed prescription medications.

3. A senior DEA official has testified in the course of other litigation that DEA made a deliberate decision in 2006-07 "to expand drug wholesalers' obligations" by requiring them—for the first time—to "suspend shipments to a customer if [they] identified an order as suspicious." *United States v. Four Hundred Sixty-Three Thousand Four Hundred Ninety-Seven Dollars & Seventy-Two Cents ($463,497.72)*, 853 F. Supp. 2d 675, 682 (E.D. Mich. 2012) (*United*

States v. $463,497.72). According to this official, DEA was concerned that this "change in policy" would confuse distributors, "since the prior 'report-only' policy [under 21 C.F.R. §1301.74(b)] had been in place for 35 years." *Id.*[2]

DEA itself maintains that it has not changed its understanding of the regulations notwithstanding the sworn testimony of a DEA official to the contrary.[3]

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[2] Q. And some of those [internal DEA] discussions were about whether or not the industry would be confused by these significant changes, correct?
A. Correct, sir.
Q. And in fact, some of those discussions were about whether your own DEA agents would be confused by these significant changes?
A. Correct, sir. …
Q. And one of the critical issues of discussion before you did these distributor briefings was, what are we going to tell distributors about this issue of whether to ship or not to ship, correct?
A. Correct.
Q. Because that was a critical issue, correct?
A. Yes, sir.
Q. And you understood at the time that you were making these decisions that it was standard practice in this industry to file suspicious activity reports while continuing to ship products?
A. Yes, sir.
Q. And in the thirty years that this rule had been on the book, the DEA never once said that that was illegal, a violation of DEA rules or regulations or anything, did it?
A. No, sir.

Transcript of Bench Trial at 384:1-8, 386:10-25, *United States v. $463,497.72*, 853 F. Supp. 2d 675, No. 08-11564 (E.D. Mich. Aug. 12, 2011), ECF No. 169 (Testimony of Kyle Wright).

[3] Q. You would acknowledge, also, sir, that in 2006 and 2007 there was a significant change in DEA policy, DEA guidance and interpretation on the very issues that are at stake in this litigation, correct?
A. Correct.

See Final Order, 80 Fed. Reg. at 55,475-76; *see also* DEA Brief 22, *Walgreen Co. v. DEA*, No. 12-1397 (D.C. Cir. Dec. 26, 2012). Yet when establishing criteria for detecting and reporting suspicious orders in 1998, DEA expressly approved a "report only" system. In describing distributors' duties regarding suspicious orders, DEA did not include any responsibility to investigate or halt shipments. According to DEA, the 1998 guidelines were "endorsed by the Attorney General and widely accepted by industry." These guidelines remained in place on DEA's website until as recently as March 28, 2013.

DEA has pointed to the adjudication in *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 Fed. Reg. 36,487, 36,498-500 (July 3, 2007) (*Southwood*), as evidence that it has previously imposed additional duties. *See* Final Order, 80 Fed. Reg. at 55,476-77 (discussing *Southwood*). In *Southwood*, DEA revoked a distributor's registration based in part on its failure to conduct adequate due diligence on its pharmacy customers. *See* 72 Fed. Reg. at 36,498-500. The decision, however, lacks a clear explanation of a distributor's duties. This is not surprising, given that the decision is the product of an adjudication. As

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Q. That's the suspicious order monitoring process, excessive orders, whether to ship or not, would you agree with me?
A. Yes, sir.
Q. And that was a significant change in your mind?
A. Yes, sir.

Testimony of Kyle Wright at 382:24-383:9.

DEA itself has explained, "the process of adjudication is not well suited" to providing "the regulated community with guidance" as to the scope of a duty. *JM Pharmacy Group, Inc, d/b/a Farmacia Nueva and Best Pharma Corp*, 80 Fed. Reg. 28,667, 28,673 (May 19, 2015). In any event, the salient point is that nowhere does *Southwood* acknowledge any change in interpretation or attempt to explain such change. *See* 72 Fed. Reg. at 36,498, 36,500, 36,502.

DEA stated in a 2006 letter to registrants that the reporting requirement of Section 1301.74(b), "is in addition to, not in lieu of, the general requirement under 21 U.S.C. § 823(e) that a distributor maintain effective controls against diversion." 2006 DEA Letter at 2, *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Sept. 27, 2006) (*Cardinal Health*), ECF No. 14-51. The letter also stated that "a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." *Id.* The 2006 letter, however, fails to explain how the statutory command of Section 823(e), a command that the Attorney General consider when adjudicating an application for registration the applicant's "maint[enance] of effective controls against diversion," became a command to registrants to engage in "due diligence" and "avoid filling suspicious orders." *Id.* Moreover, the letter fails to acknowledge that DEA was changing its interpretation or provide any explanation for the change.

In a 2007 letter to registrants sent shortly after *Southwood*, DEA stated that filling suspicious orders without first determining that the orders are not being diverted to illegitimate channels "*may* be failing to maintain effective controls against diversion." 2007 DEA Letter at 2, *Cardinal Health* (Dec. 27, 2007), ECF No. 14-8 (emphasis added). DEA never provided any guidance on when filling a suspicious order would be deemed a failure to maintain effective controls against diversion. Nor did the agency provide any guidance on how a distributor should determine if orders are being diverted to illegitimate channels. And once again, DEA failed to acknowledge, and explain, its change in position.[4]

An agency's obligation to acknowledge that it is changing position and provide a reasoned explanation for doing so is not a difficult burden to meet. But this requirement nevertheless serves a critical function by ensuring that the agency has actually considered the change, notified the public of the change, and provided

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[4] DEA's position continues to evolve. After this Court stayed the Masters Final Order, DEA issued an Order to Show Cause against another distributor, relying on the Masters Final Order to assert that a distributor was obligated to (1) "perform adequate due diligence in investigating its customers and their orders" including obtaining and analyzing a pharmacy's drug utilization report; (2) "obtain the names of any hospices, nursing homes, or physicians for whom [the pharmacy] filled controlled substances"; (3) "investigate the legitimacy of [the pharmacy's] pharmacy practice" to determine whether its customer "is filling legitimate prescriptions"; and (4) consider a geographic area's "prescription drug problem" when filling orders for customers in that area. Order to Show Cause, DEA Docket No. 16-13. This order underscores the importance of the basic administrative law issues presented by this appeal.

a reasoned explanation for it. In deciding this case, this Court should ensure that DEA has complied with this fundamental requirement.

II. AN AGENCY POSITION IS INVALID IF IT CONFLICTS WITH ITS EXISTING REGULATIONS

1. Even when an agency recognizes and explains a change in position, the new position is still invalid if it conflicts with an existing rule. *See Perez*, 135 S. Ct. at 1207-09; *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993). In deciding this case, this Court therefore also should consider whether any change in position reflected in the Final Order is inconsistent with existing regulations. In resolving that issue, the key is whether DEA's statement in the Final Order that Masters had a duty not just to *report* suspicious orders but also to *investigate* and *halt* suspicious orders works a substantive change to the preexisting regulations and, thus, is inconsistent with the regulations.[5]

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[5] A new position, adopted without notice and comment, that conflicts with or is inconsistent with an existing regulation is both *procedurally* and *substantively* invalid. It is procedurally invalid because it amounts to an amendment of a legislative rule without notice and comment. In *Perez*, the Supreme Court held that an agency's change of an *interpretation* (or interpretive rule) does not require notice and comment. 135 S. Ct. at 1206-07. The Court did not disturb, however, the rule that the *amendment* of a regulation requires notice and comment. *See id.* at 1208-09. "[I]f a second rule repudiates or is irreconcilable with a prior legislative rule, the second rule must be an amendment of the first; and, of course, an amendment to a legislative rule must itself be legislative." *Am. Mining Cong.*, 995 F.2d at 1109 (alteration in original) (citation omitted); *see also Ass'n of Flight Attendants-CWA v. Huerta*, 785 F.3d 710, 718 (D.C. Cir. 2015) (reaffirming this rule post-*Perez*). And if the existing regulation is not changed through notice and

2. a. Section 1301.71 by its terms restricts DEA's authority to delineate the requirements for "effective controls"—stating that, in evaluating a control system, the Administrator "*shall use* the security requirements set forth in §§ 1301.72-1301.76." 21 C.F.R. § 1301.71(a) (emphasis added). Nothing in Sections 1301.72-1301.76 requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.

Instead, Sections 1301.72-1301.76 make clear that a distributor's due diligence obligations are limited to (1) conducting a "good faith inquiry" to verify that the customer has a valid DEA registration, *see* 21 C.F.R. § 1301.74(a); and (2) operating a system to identify suspicious orders and inform DEA of such orders, *see id.* § 1301.74(b). And while some regulations explicitly ban distributors from actually transferring controlled substances in certain circumstances—*see id.* § 1301.74(a), (d), (g)—there is no prohibition on shipment of suspicious orders. The fact that Section 1301.71(a) specifically and explicitly requires the Administrator to use only certain provisions to judge compliance indicates that it prohibits DEA from utilizing *other* criteria not listed in the regulation.

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comment, the new, inconsistent, position is substantively invalid because an agency "must comply with its own regulations." *Environmentel, LLC v. FCC*, 661 F.3d 80, 84-85 (D.C. Cir. 2011); *see also Associated Builders & Contractors, Inc. v. Herman*, 166 F.3d 1248, 1255-56 (D.C. Cir. 1999) (setting aside agency action for failure to adhere to regulations).

This follows from a straightforward application of the *expressio unius est exclusio alterius* principle (expression of one thing is the exclusion of the other). *See, e.g.*, *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 782, 793 n.9 (1995) (requirement that Members of House of Representatives "shall" meet specific eligibility requirements bars Congress from adopting additional requirements beyond those specifically mentioned in the text); *Lewis v. Alexander*, 685 F.3d 325, 347 (3d Cir. 2012) (rejecting effort to impose new criteria for certain trusts beyond those explicitly set forth in statute because "where a specific list is set forth, it is presumed that items not on the list have been excluded"), *cert. denied*, 133 S. Ct. 933 (2013); *see also TRW Inc. v. Andrews*, 534 U.S. 19, 28-29 (2001).

This Court has applied the *expressio unius* principle to limit agency discretion in analogous circumstances. In *Ethyl Corp. v. EPA*, the Court considered the meaning of 42 U.S.C. § 7545(f)(4), a provision that empowered the EPA Administrator to waive a statutory ban on certain new fuel additives. 51 F.3d 1053 (D.C. Cir. 1995). The only criterion that the statute explicitly required the Administrator to consider in assessing a waiver request was whether the fuel additive would affect compliance with emission standards. 42 U.S.C. § 7545(f)(4). Because the statute did not *explicitly* bar the Administrator from considering other criteria not mentioned in § 7545(f)(4), the Court examined whether the

enumeration of only one specific criterion *implicitly* barred the Administrator from denying a waiver based on other factors—and concluded it did.

The Court explained that "[t]he plain language of the provision makes clear that waiver decisions are to be based on one criterion." *Ethyl Corp.*, 51 F.3d at 1058. By basing her waiver decision on public health implications, even though "[n]owhere in th[e] waiver provision is there any mention of applicants establishing or the Administrator determining a fuel additive's effect on public health," the Administrator had acted contrary to the language of the statute. *Id.* In short, EPA could not properly "apply criteria beyond those prescribed in the statute in enforcing the waiver provision," despite the lack of any explicit statutory bar on doing so. *Id.* at 1059. In fact, the Court thought that the statute so "unambiguously" prohibited consideration of "additional criteria" that it refused to grant EPA *Chevron* deference. *Id.* at 1058-60.

This case is different in one important respect. The statute in *Ethyl Corp.* *authorized* the EPA Administrator to waive certain prohibitions if the fuel additive would not affect compliance with emission standards—providing that the Administrator "*may* waive" if that condition were met. 42 U.S.C. § 7545(f)(4) (emphasis added). By contrast, the regulation here states that the administrator "*shall* use" particular requirements (i.e., those listed in Sections 1301.72-1301.76).

If anything, that distinction should strengthen the force of the *expressio unius* principle here.[6]

b. Other regulations reinforce this interpretation. When the agency promulgated Section 1301.71, DEA simultaneously enacted other provisions that explicitly gave the Administrator broad authority to consider more than the enumerated criteria. For example, 21 C.F.R. § 1301.34(c) instructs DEA on how to determine whether importers of controlled substances are satisfying their anti-diversion obligations. In stark contrast to Section 1301.71(a), Section 1301.34(c) explicitly allows the Administrator to consider additional criteria beyond those specifically listed in the regulations. 21 C.F.R. § 1301.34(c). ("In determining whether [an importer] can and will maintain effective controls against diversion ..., the Administrator shall consider *among other factors*: (1) Compliance with the security requirements set forth in §§ 1301.71-1301.76 …." (emphasis added)).

Similar catch-all formulations appear throughout the DEA regulations. At least nine other provisions require the Administrator to consider certain specifically-enumerated criteria when making a particular decision or determination, yet also include a catch-all provision expressly authorizing her to

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[6] Although *Ethyl Corp.* involved the interpretation of a statute, the *expressio unius* principle applies in interpreting regulations as well. *See, e.g.*, *United Dominion Indus., Inc. v. United States*, 532 U.S. 822, 836 (2001); *Fulani v. Fed. Election Comm'n*, 147 F.3d 924, 928 (D.C. Cir. 1998).

consider other, non-enumerated, criteria.[7] These provisions suggest that when the DEA regulations intend to grant the Administrator leeway to consider additional, unspecified criteria, they do so explicitly. *See Ethyl Corp.*, 51 F.3d at 1061 (concluding that agency had wrongly considered public health, which the statute did not list as a criterion, in making a waiver determination, when another nearby provision explicitly instructed the agency to consider public health); *see also Bates v. United States*, 522 U.S. 23, 29-30 (1997) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (citation omitted)).

Similarly, the presence of express bans on transferring controlled substances in certain circumstances in other provisions strongly indicates that no such ban applies to shipping suspicious orders. The DEA regulations clearly and explicitly specify the precise circumstances in which a distributor is prohibited from transferring controlled substances. *See, e.g.*, 21 C.F.R. § 1301.74(a) (barring transfers "to any person who the registrant does not know to be registered to possess" the substance unless the distributor first has made "a good faith inquiry" as to whether the recipient possesses such registration); *id.* § 1301.74(d) (barring

[7] *See, e.g.*, 21 C.F.R. §§ 1301.34(b), 1301.74(c), 1301.76(b), 1303.11(b), 1303.13(b), 1310.10(d), 1310.21(c), 1315.11(b), 1315.13(b).

certain transfers of free samples of drugs); *id.* § 1301.74(g) (barring certain transfers of specific chemicals). There is no such requirement in Section 1301.71.

c. The regulatory history also indicates that Section 1301.71(a)'s second sentence was intended to clarify that a distributor's compliance with Sections 1301.72-1301.76 satisfies its anti-diversion obligations.

The Justice Department originally proposed draft regulations to implement the CSA in 1971. *See Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970*, 36 Fed. Reg. 4928 (Mar. 13, 1971). The draft of Section 301.91 (the predecessor to Section 1301.71) included the statutory requirement that registrants maintain effective controls against diversion, but it did *not* explicitly limit the Administrator to any particular criteria when assessing compliance. *Id.* at 4935. Instead, it noted that the security regulations (which would eventually become Sections 1301.72-1301.76) were "intended as standards for the construction and maintenance of security facilities … [and] [s]ubstantial compliance with these standards may be deemed sufficient by the Bureau after evaluation of the overall security controls." *Id.* at 4935.

In the final rule, however, the Justice Department eliminated this grant of discretion and instead mandated that the Administrator "*shall* use the security requirement set forth" as standards. *See Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970*, 36 Fed. Reg.

7776, 7784 (Apr. 24, 1971) (emphasis added). The next sentence of the final rule is roughly the same as it was in the proposed rule, explaining that "[s]ubstantial compliance with these standards may be deemed sufficient by the Director after evaluation of the overall security system and needs of the applicant or registrant." *Id.* Thus, the Department replaced a sentence that gave the Administrator discretion by noting that the regulations were only "intended as standards" with a sentence that mandated that the Administrator "shall use" the enumerated regulations to determine compliance. *See United States v. Monzel*, 641 F.3d 528, 531 (D.C. Cir. 2011) (noting that word "shall" imposes a requirement that is "mandatory," "imperative," and "not merely precatory" (citation omitted)).

3. In addition to introducing a duty to *investigate* and *halt* suspicious orders, the Masters Final Order also expands the definition of "suspicious order" to include "the pharmacy's business model, dispensing patterns, or other characteristics that might make an order suspicious, *despite the particular order not being of unusual size, pattern or frequency*." *See* Final Order, 80 Fed. Reg. at 55,473-74 (emphasis added) (citation omitted). This transforms the duty set forth in the regulations to report suspicious *orders* into a duty to investigate suspicious *customers*. A requirement to report orders placed by customers with suspicious "business models" or another undefined customer-specific suspicious "characteristic," when the underlying order itself is "not … unusual" conflicts with

the regulation's focus on "suspicious *orders*" and the regulation's clarifying language that, in determining whether an order is suspicious, registrants should look for "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," *i.e.,* order-specific information. 21 C.F.R. § 1301.74(b) (emphasis added). Additionally, the catch-all, "other characteristics" category included in the new definition of "suspicious order" is vague and open-ended, and would allow DEA to retroactively point to any orders that it has determined to be suspicious after the fact and penalize registrants for failing to report them *ex ante*.

If the Court concludes that the Masters Final Order works a substantive change to DEA's regulations in these important respects, then the agency's imposition of these new duties and criteria would require notice and comment.[8]

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[8] To the extent that Masters agreed in its Memorandum of Agreement (MOA) with DEA to undertake obligations that are not imposed by the CSA and DEA's regulations, those obligations are not binding on distributors. If this Court determines that Masters failed to abide by its MOA, the Court should make clear that Masters' obligations under its MOA do not apply to other distributors. Nor are they appropriate factors for DEA to consider when determining whether other distributors maintain effective controls against diversion.

III. APPLYING THESE SETTLED ADMINISTRATIVE LAW PRINCIPLES IS ESPECIALLY IMPORTANT HERE

The practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.

Different entities supervise the discrete links in the chain that separates a consumer from a controlled substance. Statutes and regulations carefully define each participant's role and responsibilities. First, a patient explains his symptoms to a doctor. Second, the doctor applies her medical training and expertise to decide which medication, and in what amount, would best address that patient's healthcare needs and issues an appropriate prescription. Third, a pharmacy receives the prescription and, after a pharmacist applies her training, may dispense the medication to the patient. Fourth, in order to stock its inventory, a pharmacy purchases controlled substances from a wholesale distributor.

The orders that a pharmacy places with a distributor are based on many factors including patient needs, the pharmacy's existing inventory, potential drug shortages, pricing, cash flow, and anticipated need during weekends and holidays. A Schedule II order form (DEA Form 222) includes only the pharmacy's name, address, DEA registration number, and the amount of the substance the pharmacy

wishes to buy.[9] *See* Sample DEA Form 222, Addendum. Order forms do not contain any patient information and distributors do not and cannot know the identity of patients who received or will receive the medications dispensed by a pharmacy. Pharmacies may purchase different drugs from different distributors, or even the same drug from multiple distributors. The volume of controlled substances ordered by a pharmacy is affected by numerous factors including its proximity to or affiliation with medical facilities, the availability of other pharmacies in the area, participation in a pharmacy benefit management plan, and the hours of operation.

Distributors are legally prevented from sharing how much of a given drug or product each is selling to a given pharmacy without potentially violating antitrust laws. Without such information, an individual wholesale distributor cannot know what other entities its pharmacy customer may be purchasing from, and how much total product the customer is purchasing. Similarly, for competitive and antitrust reasons, pharmacies have been reluctant to disclose purchases made from different wholesalers. Thus, a single distributor has no reliable way of determining with

[9] DEA 222 Order forms are used solely for Schedule II controlled substances. Other controlled substances (Schedules III-V) can be ordered without this form. The information provided in ordering those products by a pharmacy from a wholesaler remains the same (*i.e.*, pharmacy's name, address, DEA registration number, and the amount of the substance the pharmacy wishes to buy).

certainty if it is a pharmacy's sole supplier of controlled prescription drugs or if that pharmacy is purchasing controlled prescription drugs from any number of other distributors. And HDMA members cannot, without risk of violating the antitrust laws, pool their sales data to determine the totality of a pharmacy's orders and assess whether the total orders are indicative of diversion occurring as a result of the conduct of prescribers, their patients, or pharmacies.

At the same time, distributors lack access to data governing individual patients, and individual doctor-patient and pharmacist-patient decisions—information that, understandably, is carefully guarded by privacy laws. Likewise, distributors lack the means to compel information from prescribers and dispensers regarding the ultimate consumer. Wholesale drug distributors, who are not licensed healthcare professionals, may not lawfully gain access to a patient's medical information, including his or her pharmacy records of controlled substance prescriptions. Physicians and pharmacists are precluded from using or disclosing a patient's personal medical information absent the patient's specific written "authorization," or in certain limited circumstances not relevant here. 45 C.F.R. §§ 164.502(a), 164.506(a), (c). It is not feasible for distributors to reliably detect diversion without this information, but they lack access to the information. DEA, however, does have access to this information—or at least the legal authority to obtain it. Accordingly, DEA's regulations had sensibly imposed a duty on

distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.

Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process. A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy. Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash.

As the existing regulations recognize, other entities and individuals in the healthcare system are better positioned to investigate and assess the legitimacy of prescriptions and take steps to halt diversion. For example, the regulations require physicians and pharmacists—but not distributors—to assume "responsibility" for "proper prescribing and dispensing" of prescription drugs. 21 C.F.R. § 1306.04(a). That regulation accords with the fact that physicians and pharmacists are providing direct patient care, including prescribing and dispensing particular medications related to their respective roles with the patient, and have access to the individual patient information necessary to provide that care. Distributors, by contrast, are not professionally trained as physicians or pharmacists and have no relationship or contact with individual patients. There is simply no practical way for distributors

to look over the shoulder of pharmacists and double-check the validity of each prescription in light of an individual patient's circumstances.

At the same time, while all agree that abusive practices should be stopped, there is also a countervailing concern: ensuring that patients who legitimately need medication have ready access to it, after it is prescribed. Imposing a duty on distributors—which lack the patient information and the necessary medical expertise—to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands. That approach, in turn, could restrict patients' access to drugs for legitimate medical needs. *See, e.g.*, Pat Anson, *Fear of DEA Causing Drug Shortages*, Pain News Network (June 30, 2015), http://www.painnewsnetwork.org/stories/2015/7/30/fear-of-dea-causing-drug-shortages.

Given the unique role that distributors occupy in the healthcare system, any attempt to impose additional obligations on them to investigate and halt suspicious orders would raise serious policy and practical issues, such as the disruption of patient access to prescribed medications. Those issues at a minimum warrant

careful and public deliberation, which is exactly what administrative law principles call for when agencies seek to change the existing rules.[10]

[10] At a minimum, given the far-reaching issues raised by the imposition of such obligations on distributors generally, if this Court does conclude that the Final Order in this case may be upheld even as to any new duties that it imposes, HDMA and NACDS urge this Court to make clear that its decision (like the Final Order) is based on the particular circumstances presented by Masters' conduct, including its alleged failure to follow its own procedures.

CONCLUSION

In deciding this case, the Court should ensure that DEA has complied with the administrative law principles discussed herein.

April 4, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 4, 2016, I caused a copy of the foregoing Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as *Amici Curiae* in Support of Neither Party to be served by electronic means through the Court's CM/ECF system on counsel for all parties, who are registered CM/ECF users.

/s/ Gregory G. Garre
Gregory G. Garre

CERTIFICATE OF COMPLIANCE WITH RULE 32

1. I certify that this brief complies with the type-volume limitations of Fed. R. App. P. 29(d) and 32(a)(7)(B) because it contains 6,107 words, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

2. I further certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally-spaced typeface using Microsoft Office Word in Times New Roman 14-point font.

April 4, 2016

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ADDENDUM

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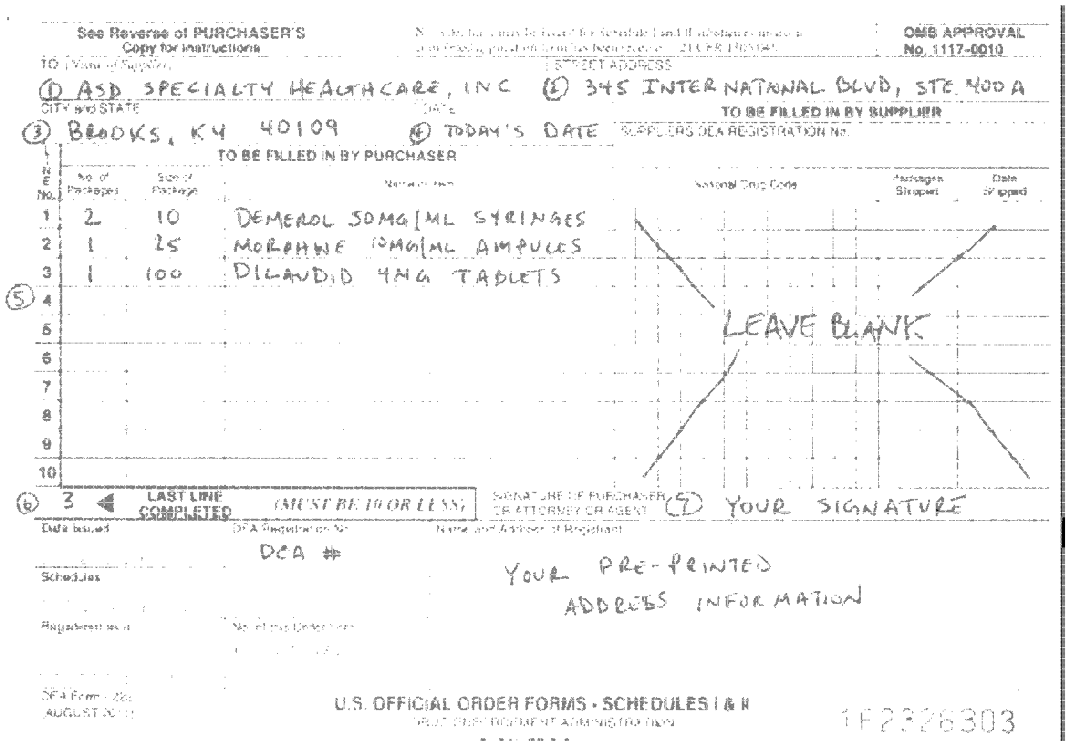

See Reverse of PURCHASER'S Copy for Instructions

OMB APPROVAL No. 1117-0010

TO (Name of Supplier)

(1) ASD SPECIALTY HEALTHCARE, INC (2) 345 INTERNATIONAL BLVD, STE 400A

CITY and STATE (3) BROOKS, KY 40109 (4) TODAY'S DATE

TO BE FILLED IN BY SUPPLIER

SUPPLIER'S DEA REGISTRATION NO.

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	2	10	DEMEROL 50MG/ML SYRINGES			
2	1	25	MORPHINE 10MG/ML AMPULES			
3	1	100	DILAUDID 4MG TABLETS			
(5) 4						
5						
6						
7						
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(6) 3 ◀ LAST LINE COMPLETED (MUST BE 10 OR LESS)

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT (7) YOUR SIGNATURE

Date Issued DEA Registration No. DEA # Name and Address of Registrant

YOUR PRE-PRINTED ADDRESS INFORMATION

Schedules

Registered with

No. of Prior Orders Filed

DEA Form 222 AUGUST 2007

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II

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